# DECLARATION OF LARRY D. SASICH

1. My name is Larry D. Sasich, PharmD, MPH, FASHP. I am over the age of twenty-one and competent to testify to the truth of the matters contained herein. The factual statements I make in this declaration are true and correct to the best of my knowledge and experience. The opinions I express in this statement are made to a reasonable degree of scientific certainty.

2. I am a Consultant specializing in drug safety and efficacy issues. My background, experience and qualifications, in part, include:

a. Serving as a consultant to the Saudi Food and Drug Authority, Riyadh, Saudi Arabia.

b. Serving as Chairperson of the Department of Pharmacy Practice at the LECOM School of Pharmacy in Erie, Pennsylvania, from 2007 to 2009;

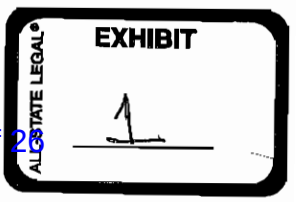
c. Serving as a consultant to Public Citizen Health Research Group, Washington, D.C., and

d. Serving as a Consumer Representative on the Science Board of Food and Drug Administration's, an advisory committee to the FDA Commissioner.

3. I have a Masters in Public Health, with an emphasis in biostatistics and epidemiology from the George Washington University, and a Doctorate of Pharmacy from University of the Pacific. I have completed a residency in nuclear pharmacy at the University of New Mexico. I have also been elected a Fellow in the American Society of Health-System Pharmacists (FASHP). I have also authored publications and/or presented analysis on drug safety issues. A complete list of my publications and presentations are listed in my Curriculum Vitae, which is appended to this Declaration as Exhibit A.

4. Counsel representing Missouri death-sentenced prisoners have asked me to provide opinions in *Zink v. Lombardi*, Case No. 12-4209 with regard to the use of compounded drugs in lethal injection. I have provided five prior declarations in this case. On January 23, 2014, counsel for one of the Plaintiffs in *Zink* asked me to review documents that had just been received and which pertained to the drugs intended to execute Mr. Herbert Smulls on January 29, 2014. The documents, which I have only had only a short time to review thus far, raise a number of questions that require further study.

5. At the bottom of some of the reports, I noted, again, that the



laboratory which tested the drugs repeated the language included in its prior reports, that its "analysis is not to be construed as a warranty, expressed or implied." Of course, this language raises questions about the validity of the test results reported. A report containing this language is attached as Exhibit B.

**Certificate of Analysis Document, Page AGO002681**

6. A Certificate of Analysis, page AGO002681 (attached as Exhibit C), warrants further attention and review as the results raise a very clear concern. This document notes that an *unknown* residual solvent was found in the sample that was tested, yet the report indicated that the sample *passed*. It is unacceptable by any standard to inject an *unknown* substance into a human subject. If a residual solvent is identified, and it is known not to be harmful to humans, then its use would be permissible. However, the injection of an *unknown* is suggestive of experimentation on a human subject. Further study is required here, and the compounding pharmacy should immediately produce its formulation sheet so the unknown solvent can be identified.

[redacted]

7. [redacted]

8. [redacted]

[redacted]

9. [redacted]

10. [redacted]

11. [redacted]

12. [redacted]

13. [redacted]

14. [redacted]

15. Clearly, there are serious problems with contract testing laboratories that call into serious question whether these companies are competent to determine if compounded drugs are safe, effective, and pure. The word testing carries weight that gives health professionals, the public, and policy makers a feeling of security if a product is tested. Great concerns arise if the reliability and validity of the testing is not deserved. These concerns are also addressed in my prior Declaration of January 17, 2014.

16. Based on facts presently known to me, it is my opinion that there is no way, at this point, to know the exact composition of the drug that will be injected into Mr. Smulls. Therefore, based on the issues noted in this Declaration and the issues discussed in my prior Declarations in the *Zink* litigation, I conclude there is a high likelihood that this drug may cause Mr. Smulls to suffer extreme pain and harm.

I declare under pains and penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Larry D. Sasich 1/24/14

Larry D. Sasich, PharmD, MPH, FASHP

# CURRICULUM VITAE

**Larry D. Sasich, Pharm.D., M.P.H., FASHP**
**839 Main Street West #3**
**North Bay, P1B 2V8, Ontario**
**Canada**
**Cell Phone: 705-491-0609**
**E-Mail: larry.sasich@gmail.com**

## EDUCATION

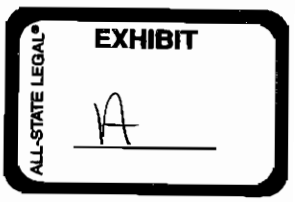
| | |
|---|---|
| 1995 to 1997 | Master of Public Health - Epidemiology<br>The George Washington University School of Public Health and Health Services<br>Washington, D.C. |
| 1974 to 1975 | Doctor of Pharmacy<br>University of the Pacific<br>College of Pharmacy<br>Stockton, California |
| 1966 to 1970 | Bachelor of Science Pharmacy<br>Idaho State University<br>College of Pharmacy<br>Pocatello, Idaho |

## RESIDENCY

| | |
|---|---|
| 1986 to 1987 | Nuclear Pharmacy<br>University of New Mexico<br>College of Pharmacy<br>Albuquerque, New Mexico |

## PROFESSIONAL LICENSES

| | |
|---|---|
| 1970 to Present | California RPH 27094 |



**PROFESSIONAL EXPERIENCE**

| | |
|---|---|
| April 2013 to date | Consultant, Drug Policy, Drug Safety and Efficacy<br>North Bay, ON Canada |
| July 2007 to April 2013 | Consultant,<br>Saudi Food and Drug Authority<br>3292 Northern Ring Rd. Al Nafal District<br>Riyadh, Saudi Arabia |
| November 2009 to 2012 | Consultant,<br>Public Citizen's Health Research Group<br>1600 20th Street, NW<br>Washington, D.C. 20009 |
| 2007 to 2009 | Chairman,<br>Department of Pharmacy Practice<br>LECOM School of Pharmacy<br>1858 Grandview Blvd.<br>Erie, PA 16505 |
| 2006 to 2007 | Acting Chairman,<br>Department of Pharmacy Practice<br>LECOM School of Pharmacy<br>1858 Grandview Blvd.<br>Erie, PA 16505 |
| 2005 to 2006 | Assistant Professor,<br>Department of Pharmacy Practice<br>LECOM School of Pharmacy<br>1858 Grandview Blvd.<br>Erie, PA 16505 |
| 2006 to 2008 | Consultant<br>Centre for Science and the Public Interest – Canada<br>Suite 4550, CTTC Bldg.<br>1125 Colonel By Drive<br>Ottawa, Ontario K1S 5R1<br>Canada |

**PROFESSIONAL EXPERIENCE**

| | |
|---|---|
| 2005 to 2007 | Consultant<br>Public Citizen's Health Research Group<br>1600 20th Street, NW<br>Washington, D.C. 20009 |
| 2005 to 2006 | Consultant<br>Canadian Agency for Drugs and Technologies in Health<br>600-865 Carling Avenue<br>Ottawa, Ontario K1S 5S8<br>Canada |
| 1995 to 2005 | Research Analyst<br>Public Citizen's Health Research Group<br>1600 20th Street NW<br>Washington, D.C. 20009 |
| 1991 to 1995 | Drug Information Pharmacist<br>King Faisal Specialist Hospital and Research Centre<br>Riyadh 11211, Saudi Arabia |
| 1993 to 1996 | Adjunct Clinical Faculty<br>Welch School of Pharmacy<br>University of Wales<br>Cardiff, Wales |
| 1992 to 1995 | Clinical Instructor<br>College of Pharmacy<br>King Saud University<br>Riyadh, Saudi Arabia<br>Graduate and Undergraduate Teaching |
| 1988 to 1990 | Clinical Pharmacist<br>St. Helens Hospital and Health Center<br>St. Helens, OR<br><br>Emanuel Hospital and Health Center<br>Portland, OR |
| 1985 to 1988 | Associate Professor of Clinical Pharmacy<br>Idaho State University<br>College of Pharmacy<br>Pocatello, Idaho<br><br>Promoted and Tenured July 1, 1984 |

## PROFESSIONAL EXPERIENCE

| | |
|---|---|
| 1983 to 1984 | Assistant Professor of Clinical Pharmacy<br>College of Pharmacy<br>Idaho State University<br>Pocatello, Idaho |
| | Acting Associate Dean for Student Affairs |
| 1982 to 1983 | Assistant Professor of Clinical Pharmacy<br>College of Pharmacy<br>Idaho State University<br>Pocatello, Idaho |
| | Director of Professional Practice |
| 1979 to 1982 | Assistant Professor of Clinical Pharmacy<br>College of Pharmacy<br>Idaho State University<br>Pocatello, Idaho |
| | Director, Idaho Drug Information Service and Regional Poison Control Center |
| 1976 to 1979 | Assistant Director of Pharmacy Services<br>USA MEDDAC<br>Berlin, West Germany |
| 1975 to 1976 | Staff Pharmacist<br>USA MEDDAC<br>Wuerzburg, West Germany |
| 1970 to 1974 | Pharmacist<br>Baneth's Pharmacy<br>Menlo Park, CA |

## HONORARY SOCIETIES

| | |
|---|---|
| 1982 | Rho Chi |
| 1982 | Sigma Xi |

**AWARDS**

| | |
|---|---|
| 2000 | Distinguished Person of the Year – Pharmacists Planning Services |
| 1995 | Fellow American Society of Health-System Pharmacists |
| 1986 | Ciba-Geigy Leadership Award |
| 1983 | Outstanding Service – Idaho Board of Pharmacy |
| 1982 | Phi Delta Chi Faculty Achievement Award |

**APPOINTMENTS**

| | |
|---|---|
| 2009 | FDA Science Board Sub Committee on the Center for Food Safety and Applied Nutrition (CFSAN) |
| 2008 | FDA Science Board Sub Committee on the review of the National Center for Toxicological Research |
| 2007 | Grant Reviewer<br>U.K. Economic and Social Research Council<br>Large Grant proposal: Governance of Pharmaceuticals and Health |
| 2007 | Consumer representative, Science Board to the Food and Drug Administration – advisory committee to the FDA Commissioner |
| 2007 | Pennsylvania Pharmacists Association Pharmacy Compounding Task Force |
| 2006 | Food and Drug Administration Pediatric Advisory Committee November 16, 2006 – substitute consumer representative |
| 2006 | Reviewer *PLoS Medicine* |
| 2000 | Reviewer for the *Western Journal of Medicine* |
| 2000 | Reviewer for the *Journal of the American Medical Association* |
| 1996 | Department of Health and Human Services Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Drug Information |
| 1996 | Department of Health and Human Services, Food and Drug Administration, Consumer Consortium |

**APPOINTMENTS**

| | |
|---|---|
| 1995 | Reviewer for the *Saudi Pharmaceutical Journal* |
| 1993 | Reviewer for the *Annals of Saudi Medicine* |
| 1986 | Reviewer for *Annals of Pharmacotherapy* |
| 1987 | Idaho Delegate to Western Regional Conference on Clinical Pharmacy Practice |
| 1985 | Idaho Health Systems Ethics Conference Task Force |
| 1984 | American Pharmaceutical Association Committee to prepare accreditation standards for a community pharmacy residency |
| 1982 | Assistant Editor DRUGDEX® |
| 1981 | USP Dispensing Information Contributors Panel |

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Sasich LD. Rapid Response: Tamiflu: 14 flu seasons and still questions. BMJ 2013. At http://www.bmj.com/content/346/bmj.f547?tab=responses. Accessed January 28, 2013.

Sasich LD, Sukkari SR. The US FDA's Withdrawal of the Breast Cancer Indication for Avastin (Bevacizumab*). Saudi Pharmaceutical Journal* 2012; 20: 381-385.

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Tuttle DA, Sasich LD, Sukkari SR. Improving Access to FDA Reviews and Documents. *Journal of the American Medical Association* 2009; 302: 2204.

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Sasich LD, Barasain MA, Al Kudsi MA. Three country comparison of selected safety information in the prescribing information for rosiglitazone (Avandia). *Saudi Pharmaceutical Journal* 2009; 17: 195-198.

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Sasich LD, Wolfe SM, Pearson C, Swankin DA, Levin DA, Levin AA, Beard J. The National Council on Patient Information and Education. *Journal of the American Medical Association* 278:1491-1492; 1997[letter].

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Sasich L, Morriss HA. A computerized on-line key word indexing system for drug information retrieval. *Hospital Pharmacy* 16:136; 1981.

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Wolfe SM, Sasich LD, Hope R-E. *Worst Pills, Best Pills*. New York: Pocket Books, 2005.

Sasich LD, Sukkari SR. Drug induced blood disorders. In: Applied Therapeutics: the Clinical Use of Drugs. Young, LY, Koda-Kimble, M eds. Baltimore: Lippincott, Williams & Wilkins, 2004.

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Sasich LD, Sukkari SR. Drug induced blood disorders. In: Applied Therapeutics: the Clinical Use of Drugs 6th ed. Young, LY, Koda-Kimble, M eds. Baltimore: Lippincott,

**BOOKS AND CHAPTERS**

Williams & Wilkins, 2001.

Wolfe SM, Sasich LD, Hope R-E. *Worst Pills, Best Pills*. New York: Pocket Books, 1999.

References available on request

[redacted]

# CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII

[redacted]

MFG. DATE: 05/20/2011
EXPIRATION: 05/20/2016

CAS: 57-33-0
MW: [redacted]
FORMULA: C11H17N2NaO3

14.042gm
USED
MADE 280ml
FOR TESTING
+ Rx

| TEST | SPECIFICATIONS | RESULTS |
|---|---|---|
| Aerobic Plate Count Bact | <300 cfu/g max<br>*Alert at 100 CFU/g* | 50 cfu/g max |
| Aerobic Plate Count Fung | <300 cfu/g max<br>*Alert at 100 CFU/g* | 50 cfu/g max |
| Assay | 98.0-102.0 % | 99.2 % |
| Baterial Endotoxins | <0.8 eu/mg max | 0.08 eu/mg max |
| Completeness of solution | pass<br>*after 1 minute, the solution is clear and free from undissolved solid.* | pass |
| Description | pass<br>*White, crystalline granules or white powder; odorless or has slight characteristic odor; slightly bitter taste; solutions decompose on standing, heat accelerating the decomposition; aq solns are unstable* | pass<br>*White powder; odorless* |
| Free Pentobarbital | <=3.5 % | 0.4 % |
| Heavy metals | <= 0.003 % max | 0.003 % max |
| Identification | pass<br>*A: UV- Passes test B: Passes test, C: Passes test for Sodium.* | pass |
| Loss on drying | <=3.5 % | 0.3 % |
| OVI | pass<br>*meets the requirements.* | pass |
| pH | 9.8-11.0 | 10.3 |
| Related compounds | pass<br>*6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: NMT 0.2% 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: NMT 0.1% 5-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: NMT 0.3% UNKNOWN IMPURITIES: NMT 0.1% TOTAL: NMT 0.5%* | pass<br>*6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: <0.05% 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: <0.05% 5-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: <0.05% UNKNOWN IMPURITIES: <0.05% TOTAL: <0.05%* |
| Residual Solvents-Ethano | <0.5 % max | 0.1002 % max |

ALL-STATE LEGAL® EXHIBIT B

QC APPROVED
PRINT DATE: 1/22/2014
PAGE: 1 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
This analysis is not to be construed as a warranty, expressed or implied.

# Certificate Of Analysis

CLIENT:

LOT #:
DESCRIPTION: S-Pentobarbital Sodium 50 mg/mL Inj Sol
DATE RECEIVED: 01/08/2014
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: One 60mL syringe w/ 35mL and one 10mL syringe w/ 5mL in brown bags

| Test | Test Method | Limits | Results | Date Tested |
|---|---|---|---|---|
| Identification (HPLC-Retention time) | USP 36 | Conforms to USP Specifications | Conforms | 01/22/2014 |
| pH <791> | USP 36 | 9.0 - 10.5 | 9.429 | 01/14/2014 |
| Particulate Matter <788> | USP 36 | 10µm<=6000/cont; 25 µm<=600/cont | 10µm=0/cont; 25 µm=0/cont | 01/14/2014 |
| Assay (HPLC) | USP 36 | 92.0% - 108.0% | 97.0% | 01/22/2014 |
| Residual Solvents "A" <467> (GC) | USP 36 | See *Note | Pass | 01/22/2014 |

Formulation ID:

*Note: As per USP 36 General Chapter <467>, Residual Solvents Procedure A, Sample passes. However, it is noted there is a peak at retention time 3.610 that does not match any known standard in Procedure A. Peak is identified as unknown. Test performed as per USP 36 General Chapter <467> Water-Soluble Articles Procedure A.

01/22/2014
Date Reported

EXHIBIT
ALL-STATE LEGAL®
C

*Results reported above relate only to the sample that was tested.*

# Microbiology Report

**CLIENT:**

**ARL #:**

**LOT #:** [redacted]

**DESCRIPTION:** Pentobarbital Sodium 50 mg/mL Solution

**DATE RECEIVED:** 11/07/2013

**STORAGE:** 20°C to 25°C (68°F to 77°F)

**CONTAINER:** Two 10 mL syringes w/ 5mL each in brown bags

| ANALYSIS | Limits | Results | Test Method | Date Tested |
|---|---|---|---|---|
| Sterility (*Preliminary*) | Sterile / Not Sterile | No Growth at 7 Days | MBI-144 | 11/07/2013 |

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

*Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.*

*Fungus – This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.*

*Endotoxin - To calculate the endotoxin limit use the following formulas: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg*
*Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)*
*Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.*
*Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour x 1.80 m2)/70 Kg.*

11/11/2013

Date Reported

*Results reported above relate only to the sample that was tested.*



EXHIBIT D

ALL-STATE LEGAL

# Microbiology Report

**CLIENT:**

**ARL #:**
**LOT #:**
**DESCRIPTION:** S-Pentobarbital Sodium 50mg/mL Inj Sol
**DATE RECEIVED:** 11/27/2013
**STORAGE:** 20°C to 25°C (68°F to 77°F)
**CONTAINER:** Two 20 mL syringes with 15 mL each in a brown bag

| ANALYSIS | Limits | Results | Test Method | Date Tested |
|---|---|---|---|---|
| Sterility (*Preliminary*) | Sterile / Not Sterile | No Growth at 3 Days | MBI-144 | 11/29/2013 |

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

12/02/2013
Date Reported

*Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.*

*Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.*

*Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg*
*Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)*
*Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.*
*Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.*

*Results reported above relate only to the sample that was tested.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 4040 N. Central Expressway, #300<br>Dallas, TX 75204<br>214-253-5200<br><br>Industry Information: www.fda.gov/oc/industry | 10/12/12-11/08/12<br><br>FEI NUMBER<br>[redacted] |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: [redacted]

| FIRM NAME | STREET ADDRESS |
|---|---|
| [redacted] | [redacted] |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| [redacted] | [redacted] |

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

The following observations pertain to the firm's contract testing of human drug products, including compounded drug products.

1. Your firm states on the Microbiology Report that is issued to a client after sterility and/or fungal testing that the Test Method employed was USP <71>. However, your firm is not fully following all parts of USP <71> when performing sterility and/or fungal testing of human drug products. For example,

a. USP <71> requires a Method Suitability Test be performed for all new products tested. Your firm does not have documentation to show that Method Suitability Testing has been performed for all drug products submitted for sterility testing by [redacted] both located in [redacted]. For those drug products submitted by [redacted] you have some documentation of bacteriostasis/fungistasis testing performed in 2006 & 2008 on a limited number of drug products, however there is no source documentation showing how the tests were performed, lot numbers of organisms or media used, and who performed the testing.

b. USP <71> specifies the number of articles to be tested. While you provide reference to USP <71> for sample sizes, you do not ensure that your clients are submitting the required number of articles for testing. Most clients usually submit only (b) (4) for sterility testing, including [redacted].

2. Your firm has no documentation to show that all analytical methods used to test for potency (assay) have been validated for all drug products including drug products submitted for testing by [redacted] These include drug products such as Methylprednisolone Acetate, Heparin, Vasopressin, Triamcinolone Acetonide, and products containing Bupivacaine and Epinephrine. Analytical methods that are not validated and/ or not found in the USP that are used for potency testing of human drug products are not written, reviewed and approved.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (*Print or Type*) | DATE ISSUED |
|---|---|---|---|
| | [redacted] | [redacted] | 11/8/12 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 4040 N. Central Expressway, #300<br>Dallas, TX 75204<br>214-253-5200<br><br>Industry Information: www.fda.gov/oc/industry | 10/12/12-11/08/12 |
| | FEI NUMBER [redacted] |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: [redacted]

| FIRM NAME | STREET ADDRESS |
|---|---|
| [redacted] | [redacted] |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| [redacted] | [redacted] |

3. Your firm states on the Microbiology Report that is issued to a client after endotoxin testing that the Test Method employed was USP <85>. Your firm is not fully following all parts of USP <85> when performing endotoxin testing of human drug products.

Specifically, the Maximum Valid Dilution (MVD) is not always calculated using the formula in USP <85>. Your firm does not ensure that each of your clients provides information regarding dosing of the drug product needed to calculate the MVD. For example,

a. An endotoxin limit was not established for Clonidine/Ropivacaine (PF) 1mcg/1mg/ml in 500mL 0.9% Sodium Chloride (injectable) submitted as sample #186092-01 by [redacted] and tested for endotoxins on 9/4/12.

b. An endotoxin limit was not set for Baclofen PF (STOCK) 5000 mcg/mL Injection submitted as sample #184445-01 by [redacted] and tested for endotoxins on 9/4/12.

c. An endotoxin limit was not set established for CP2D submitted as sample #176189-01 by [redacted] and tested for endotoxins on 5/18/12.

4. Your firm has had 13 confirmed endotoxin failures for various drug products from October 2010-October 2012. There is no documentation of any investigations conducted into any endotoxin failures, including the failure of sample #186077-01 of Sodium Bicarbonate 150mEq/1000mL in Sterile Water for Injection that was submitted by [redacted]. SOP MBI-126 Microbiology Out-of-Specification Investigation (OOS), does not address investigation of OOS's for endotoxin testing.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (*Print or Type*) | DATE ISSUED |
|---|---|---|---|
| | [redacted] | [redacted] | 11/8/12 |

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The Washington Post

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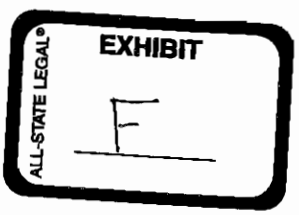
# Labs that test safety of custom-made drugs fall under scrutiny

**By Kimberly Kindy, Published: October 5**

Thousands of contaminated or potentially tainted medications have made it to market over the past year after laboratories responsible for testing custom-made pharmaceutical products failed to follow proper procedures, FDA records show.

The Food and Drug Administration uncovered the problems during a series of surprise inspections at dozens of specialty pharmacies over the past year, prompted by last fall's deadly meningitis outbreak tied to tainted steroid injections made by one of the pharmacies, New England Compounding Center (NECC).

The FDA found unsanitary conditions and sloppy procedures at 60 specialty pharmacies. Behind each one of these pharmacies, known as compounders, independent testing laboratories were affirming that the drugs were safe, sterile and mixed at the proper strength, FDA records show.




The FDA cited five labs for more than 70 safety problems, including one case in which the repeated appearance of bacteria in a so-called clean room where sterile drugs were being tested called into question the integrity of the testing procedures.

The five laboratories conduct testing for about 90 percent of the nation's large-scale specialty pharmacies, which mass-produce custom-mixed drugs and other medical solutions for doctors, clinics and hospitals.

Dozens of types of medications, packaged in thousands of IV bags, syringes and vials, have been recalled as a result of FDA inspections at the compounding pharmacies and the laboratories they use.

One of the labs, Oklahoma-based Analytical Research Laboratories (ARL), reported favorable test results for medications for the now-shuttered NECC, which produced the steroids that federal health officials say killed 64 people and sickened 686 other people last fall.

Another facility, DynaLabs in Missouri, tested and reported that a calcium gluconate solution, made by Texas-based Specialty Compounding, was safe and effective. Federal authorities said they believe the solution supplied by Specialty Compounding was contaminated with bacteria. Dozens of batches of that solution, commonly used to stabilize calcium levels in heart patients, were recalled by the pharmacy in August after the Centers for Disease Control and Prevention linked it to two deaths and 13 illnesses at two Texas hospitals.

The FDA has not assigned blame for the contaminated medications exclusively to the labs but said they must play an essential role in ensuring public safety.

"They were supposed to be a safety net, but no one has been policing the labs," said Eric Kastango, a national expert on compounding and compounding industry consultant.

Unlike small pharmacies that custom mix medications based on an individual patient prescription, large-scale compounding firms make their custom-mixed products in sizable quantities and often ship them across state lines.

These large firms, like NECC, began routinely turning to independent laboratories for outside validation a decade ago. The move followed a series of scandals, including one in 2001 where thousands of cancer patients were given chemotherapy treatments by a Kansas City compounder who had diluted them to 40 percent below their prescribed strength.

To validate the sterility and potency of medical products, laboratories rapidly expanded their operations, and new laboratories began springing up, offering certificates that compounders provide to clients showing that products passed external testing.

Although court cases have produced conflicting rulings about which regulators have authority over the compounders — state pharmacy boards or the FDA — no one has ever claimed full authority over laboratories that contract with the specialty pharmacies.

Compounding experts say state pharmacy boards have neither the legal authority nor expertise to inspect the facilities. And the FDA, which lacks clear oversight authority, has rarely gone in unless there is a reported problem or if the lab has voluntarily registered with the agency.

Late last month, House and Senate committees agreed on legislation that would give the FDA greater authority over large-scale compounding pharmacies, but agency officials said the bill does not address the testing labs.

In the wake of the meningitis crisis, the FDA has come under pressure from Congress and government watchdog groups to increase oversight of the compounders since dozens of compounding pharmacies are functioning like manufacturers, mixing large batches of medications without prescriptions for specific patients.

"We saw a number of concerning practices that cast a lot of doubt on the validity of their sterility and other test results," said Howard Sklamberg, director of compliance for the FDA's Center for Drug Evaluation.

In interviews, officials with three of the laboratories cited by the FDA defended their practices. They also asserted that they do not fall under the FDA's authority and that they and their clients should not be judged by

the standards that apply to manufacturers.

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"We think compounders should test, absolutely," said Jennifer Travis, co-owner of Front Range Laboratories in Colorado. "We want safer drugs, too, but we don't think those standards apply to us. The biggest problem right now, though, is we are operating in a crazy gray area."

After the meningitis outbreak, the FDA conducted inspections of 66 compounders, leading to 22 recalls overseen by the agency and five more by state health officials. This level of activity is a dramatic escalation for the FDA, which had conducted an average of 20 inspections of compounders a year and rarely inspected the labs they use.

The FDA's first laboratory inspection came last October, days after the FDA officials saw filthy conditions at Massachusetts-based NECC that included visible mold in injectable steroids that ended up being fungus, FDA records show. The agency also found vermin in rooms where sterile drug products were being made at NECC's sister company, Ameridose, which has also since closed.

Both compounders used the ARL lab, and within days of the outbreak, FDA officials were at the ARL facility in Oklahoma City. The agency cited the lab for failing to keep records for much of the bacterial and fungal testing it performed for NECC and Ameridose. Among other things, FDA inspectors could not determine how tests were performed or which ARL employees did the tests, information that allows labs to perform internal audits when problems arise.

ARL spokesman Brent Gooden said in a statement that the company "promptly addressed each observation listed during the recent inspection, which were primarily focused on increasing documentation." In a written statement, the lab also said that after it reviewed the FDA's inspection reports for NECC and Ameridose, lab officials concluded that the two companies had sent them partially processed steroid products and that contamination was likely introduced at a later stage of production.

Two weeks after FDA inspectors visited ARL, a different team of federal inspectors arrived at DynaLabs. In its report, the FDA cited the laboratory for not having basic procedures in place that would "prevent microbiological contamination of drug products purporting to be sterile."

Russell D. Odegard, managing partner with DynaLabs, said the company has "implemented the necessary improvements" in response to the FDA visit and is addressing the "quality concerns" raised by inspectors.

The laboratory tested the calcium gluconate solution that was made by Specialty Compounding, which the Centers for Disease Control and Prevention linked this summer to the deaths and illnesses in Texas. Specialty Compounding spokesman David Ball said the company thinks the testing was reliable and that contamination could have been introduced at some other point.

Also last fall, FDA officials examined Boston Analytical in Salem, N.H. A November report shows the FDA faulted the lab for failing to investigate client complaints in a timely manner and for failing to use testing methods that reliably assess the "strength, quality and purity" of products.

Officials from Boston Analytical did not return calls seeking comment.

In June, FDA inspectors examined another laboratory, Eagle Analytical Services in Houston. Two weeks later, the agency issued a report that said the lab did not have "scientifically sound" testing procedures in place and had

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poor record keeping and inadequate staff training.

No products were recalled as a result of this inspection. FDA officials said their investigation into Eagle is continuing and would not comment on it.

Eagle's general manager said he does not think the company should have to conform to legal safety standards that apply to drug manufacturers — called Good Manufacturing Practices — but that in most cases, the company has agreed to make the changes recommended by the FDA.

"We are using good science," J.D. Willey said. "For the things that made sense for us to change, we changed them, but for others we did not." For example, in its written response to the FDA, Eagle said it would not start asking clients for information regarding the batch size of medications it is testing for them.

The FDA cited three labs — ARL, DynaLabs and Eagle — for failing to ask their clients for batch size information, which is used to calculate how much product should be tested. Such data are important, federal regulators say, if labs are to produce scientifically reliable test results.

Labs say they traditionally rely on the compounding pharmacies to supply the proper amount of material for testing.

The latest laboratory to face FDA scrutiny is Front Range Laboratories. The August inspection produced a highly critical report, prompting the recall of products by at least four compounders that used Front Range. There have been no reports of patient illnesses or deaths associated with any of the medications.

The agency issued a public alert Aug. 21, telling the 100 pharmacies in 32 states that use the lab to "not use this firm for sterility and other quality attributes testing at this time."

In its report, the FDA said Front Range's testing methods were "not scientifically valid." It also cited concerns about how the company was disinfecting a room where sterile products were being tested since the company's own data showed a reoccurrence of multiple strains of bacteria surfacing in the room.

Travis, the company's co-owner, said many of the problems were being corrected when the FDA showed up and were caused, in part, by the company's move three weeks earlier to a bigger building to keep pace with the growing demand from compounders.

"We were just getting our systems up and running when they showed up," Travis said. "I also believe we looked worse than our competitors because we kept better data, and it was used against us."

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